



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,926	09/29/2003	Gregory L. Sundberg	279.666US1	7372

21186 7590 08/24/2009
SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
----------	--------------

3762

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

08/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
request@slwip.com

Art Unit: 3762

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-18, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 8, the use of “wherein the fixation helix and piston form a drive mechanism...that rides along the guide”, in combination with the other elements in the claim(s), was not described in the original disclosure. In addition, the subject matter of claim 15 not described in the original disclosure is “the drive mechanism including one or more helical drive grooves” in combination with the other elements in the claim(s).

The original disclosure only discussed the fixation helix forming the drive mechanism (e.g. page 2 and page 7 of the specification) and the figures or specification do not show/describe the drive mechanism of a piston riding along the guide.

Claim Objections

Claims 1-6 and 19-24 are objected to because of the following informalities: In claims 1 and 19, “including one or more helical drive grooves” is unclear as to what element “including” is modifying. It is suggested to state that the first portion of the fixation helix has the one or more helical drive grooves. Appropriate correction is required.

Art Unit: 3762

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-11, 13, and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping (4282885) or Fahlstrom et al (4913147).

Peers-Travarton shows housing, 12, piston, 40, helix coupled to piston (e.g. figure 2, 30), with a housing portion including a helical segmented guide, 32, that rides along the drive mechanism/helical drive grooves (e.g. figure 2, col. 4, lines 10-15), and includes a sleeve of radiopaque material coupled to the housing through the lead. (See below for the rest of the rejection).

And claims 1-6, 8, 11, and 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon in view of Bisping (4282885) or Fahlstrom et al (4913147). See, for example, figures 4-9 and corresponding description of Vachon that show the piston, helix coupled to the piston, and guide riding in the drive grooves of the helix/first portion of the helix.

Peers-Travarton or Vachon discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping or Fahlstrom teaches that it is known to put nearly the entire part of the fixation helix wire in a

Art Unit: 3762

helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton or Vachon, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping or Fahlstrom since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and/or extraction. In addition, for claim 12, the claim is a product by process limitation and does not add any further structural limitations to the final product of the helix coupled to the piston. In the alternative, it is well known when connecting two elements to make one diameter smaller than the other diameter to provide the predictable results of a more secure and tight fit of the two elements.

In the alternative for claims 6 and 21, Peers-Travaton or Vachon in view of Bisping or Fahlstrom discloses the claimed invention but does not disclose expressly 1/3 to 1/2 of the a diameter of the helix within the piston. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Peers-Travaton or Vachon in view of Bisping or Fahlstrom with 1/3 to 1/2 of the a diameter of the helix within the piston, because Applicant has not disclosed that 1/3 to 1/2 of the a diameter of the helix within the piston provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform

Art Unit: 3762

equally well with the wire completely in the recess as taught by Peers-Travatton or Vachon in view of Bisping or Fahlstrom, because it securely holds the wire during implantation.

Therefore, it would have been an obvious matter of design choice to modify Peers-Travatton or Vachon in view of Bisping or Fahlstrom to obtain the invention as specified in the claim(s).

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Peers-Travatton discussed above for claim 14 or over Peers-Travatton for claims 15 and 16. The modified Peers-Travatton or Peers-Travatton discloses the claimed invention except for the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable heart lead as taught by the modified Peers-Travatton or Peers-Travatton, with the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix since it was known in the art that medical leads use a conductor electrically connected to the piston, piston electrically connected to the helix, and active helix to provide the predictable results of a helical fixation lead that actively directly stimulates cardiac tissue at the fixation site and allows for bipolar pacing and sensing.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travatton in view of Bisping (4282885) or Fahlstrom et al. Peers-Travatton discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping or Fahlstrom teaches that it is known to put nearly

Art Unit: 3762

the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping or Fahlstrom since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and extraction.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Vachon as discussed above. The modified Vachon discloses the claimed invention except for the guide being a segmented helical guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by the modified Vachon, with the guide being a helical segmented guide since it was known in the art that implantable leads use a guide being a helical segmented guide to provide the predictable result of easily and smoothly advancing the helix from the lead.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. In addition, the argument that Bisping does not show a piston is not persuasive since a piston is just a mechanical device

Art Unit: 3762

that has up/down or thrusting/plunging motion, which core 23 of Bisping (figure 6 and 7) meets.

In addition, Fahlstrom shows in figures 20 and 21, the fixation helix in the recessed part of piston, 33.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
8/15/09